EXTRAORDINARY

GOVERNMENT

REGISTERED NO. P.III

GAZETTE

KHYBER PAKHTUNKHWA

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GOVERNMENT OF THE KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

NOTIFICATION

Peshawar, dated the 9th May, 2017.

No. SO (Drugs)/HD/2-43/2017: In exercise of the powers conferred by sub-section (1) of Section 44 of the Drugs Act, 1976 (Act No. XXXI of 1976), the Chief Minister Khyber Pakhtunkhwa Province, is pleased to make the following amendments in the N.W.F.P Drugs Rules, 1982.

AMENDMENTS

1. In rule 2, after clause (k), the following new clauses shall be added, namely:

   (l) "medical store" means a premises where drugs are stored, sold or offered for sale, and bear a license on Form 9;

   (m) "manufacturer" means a manufacturer of drugs having valid drug manufacturing license;

   (n) "Registered Medical Practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance, 1962 (XXXII of 1962);

   (o) "seller" means the seller of drugs having valid drug sale license;

   (p) "retail sale" means a direct sale to consumer; and

   (q) "whole sale or distributor" means a person who buys drugs for the purpose of selling the same to retailers(s) and includes only the authorised agents of manufacturer, importer, or indenter entitled to issue warranty in accordance with clause (i) of sub-section (1) of section 23 of the Act.".

2. In rule 4,-

   (I) In sub-rule (1), the word "Pakistani" shall be deleted;

   (II) In sub-rule (2),-

      (a) the word "Pakistani" shall be deleted; and

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(b) the provisos there under shall be deleted; and

(iii) sub-rule (3) shall be deleted.

3. In rule 6, after sub-rule (3), the following new sub-rule shall be added, namely:

"(4) Drugs for which testing facilities are not available in the laboratory, an Analyst shall conduct test analysis of samples of drugs in any other laboratory, after its declaration and authorization by the Board, for the purpose of the Act.".

4. For rule 14, the following shall be substituted, namely:

"**14. Application for licence to sell drugs and fees therefor.**---
(1) Application for the grant or renewal of a licence referred to in rule 15 shall be made on relevant Part A, B, C and D of Form 8 to the Licensing authority alongwith the fee deposit as follows:

(a) four thousand rupees for the grant of a licence specified in clause (i) and (iii) of rule 13;

(b) five thousands rupees for grant of licence specified in clause (iv) of rule 13;

(c) eight thousands rupees for grant of licence specified in clause (ii) of rule 13; and

(d) fee for renewal of such licences shall be half of the aforesaid fees, subject to fulfilment of licensing conditions.;

(2) A fee of one thousand rupees shall be paid for any change of proprietor of qualified persons or a duplicate copy of the licence, if the original is defected, damaged or lost, and such copy of the licence shall bear the words "duplicate copy and shall only be valid for remaining period.".

5. In rule 16, the full stop appearing at the end shall be replaced by a colon and thereafter the following proviso shall be added, namely:

"Provided that where a licence has been granted in respect of a place under this rule, then the licence shall also be applicable to a godown maintained by the licencee for the purpose of storage of the drugs, subject to meeting of all storage conditions, and entry with complete address shall be made in the respective licence.".

6. For rule 17, the following shall be substituted, namely:

"(1) A licence issued under these rules shall, unless sooner suspended or cancelled, remain in force for two years from the date of issue or until the disposal of the application for renewal of such licence whichever is later.

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(2) An application of renewal of a licence shall be made within one month of the expiry thereof, if not so made the licence shall stand cancelled.

(3) The Licensing authority, shall dispose off an application for issuance or renewal of licence within forty-five (45) days of receipt of an application, after fulfilment of requirements under the Act or these rules:

Provided that if the pre conditions so required are fulfilled by an applicant, the license shall be issued immediately without waiting for specified time limit.

(4) If the Licensing authority fails to dispose off the application within the specified time, reasons of failure shall be recorded.

(5) If in the opinion of Licensing authority, it is not expedient in public interest to grant a licence, it may reject an application.

(6) If the premises of the applicant do not fulfil the requirements, laid down in these rules, the Licensing authority shall in writing communicate the shortcomings to the applicant indicating the time period for the rectification, which shall not exceed beyond 30 days.

(7) The Licensing authority, shall not issue or renew a licence without an inspection report of the Inspector concerned.".

7. For rule 18, the following shall be substituted, namely:

"(1) The Licensing authority shall not issue licences, unless,-

(a) the premises have proper and adequate facilities including refrigeration, air conditioning and for their protection from direct sunlight, dust or dirt required for the storage of drugs;

(b) the premises is clean, hygienic and in tidy condition;

(c) in case of Pharmacy, the requirements laid down in Schedule "F" are complied with;

(d) in case of medical store the covered area shall not be less than 120 square feet with minimum breadth of 10 feet and height of 8 feet;

(e) in case of Pharmacy and distribution, the proprietor has appointed a person registered under clause (a) of sub-section (1) of section 24 of the Pharmacy Act 1967 (XI of 1967) while in case of medical store a qualified person registered under clauses (a) and (b) of sub-section (1) of section 24 of the Pharmacy Act, 1967, to personally supervise the sale of drugs; and

(f) in case of license for distribution by way of whole sale on Form 10, the applicant is an indenter, importer, manufacturer or distributor of drugs and the premises shall fulfil the requirements contained in Schedule H;

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Provided that the provision of Rule 18 (1) (d) shall not have any effect on the licenses issued prior to the notification of these rules till its expiry.

Provided further that the provision of Rule 18 (1) (e) shall not be applicable to the existing licenses till its expiry.

(2) The Licensing authority shall not issue license, if the applicant has been convicted under sub-section (1) of section 27 of the Act.".

8. In rule 19,-

(i) in sub-rule (1),-

(a) after the figure "9" the figure "10" shall be added;

(b) for clause (c), the following shall be substituted, namely:

"(c) the purchase and sale of any drug specified in Schedules "B" and "D" by way of retail sale shall be recorded at the time of purchase and dispensing in a register specially maintained for the purpose and the following particulars shall be entered in the register, namely:

(i) serial number;
(ii) date of purchase/sale;
(iii) invoice number;
(iv) name of the drug;
(v) name of the manufacturer;
(vi) batch number;
(vii) quantity purchased;
(viii) name and age of the patient;
(ix) name of the prescriber;
(x) name of the hospital/clinic;
(xi) quantity sold;
(xii) quantity remained; and
(xiii) signature of the qualified person;".

(c) after clause (c), as so amended, the following new clauses shall be added, namely:

"(d) subject to sub rule (1), a medical store, having licence bearing qualified person registered under clause (b) of sub-section (1) of section 24 of the Pharmacy Act, shall not sell or store drug(s) as mentioned in Schedule G; and

(e) in case of a Pharmacy, the person shall display the word Pharmacy on its outside in a white writing on red coloured sign board having minimum length 5 feet and width of 2.5 feet. The person shall display the word Medical Store in white writing on a Green colour sign board with same minimum dimension as required in case of Pharmacy, and the person shall display the word "wholesale/distributor" in black writing on a Blue Colour sign board with same minimum dimensions as required for a pharmacy.";

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(ii) for sub rule (4), the following shall be substituted, namely:

"(4) The manufacturer, importer or distributor of a drug shall maintain record of purchase or sale of a drug and shall preserve the record for at least three years containing the following particulars, namely:

(a) the date of purchase and sale;

(b) the name and address of the concern from which purchased and the concerns to whom sold;

(c) the name of the drugs, their batch number, their dates of expiry where applicable and the quantities; and

(d) the name of the manufacturer."; and

(iii) after sub-rule (9), the following sub-rules shall be added, namely:

"(10) A manufacturer, importer or the distributor of a drug shall sell the drug only to a holder of a valid drug sale licence and shall issue an invoice and warranty at the time of sale of the drug.

(11) The licensee having licence in Forms 9, 10, 11 and 12 shall ensure that warranty in the Form for every batch of drug so procured is obtained in accordance with the provisions of the clause (i) of sub-section (1) of section 23 of the Act;

(12) The licensee holding license on Forms 9, 10, 11 and 12 shall be required to ensure storage of the allopathic drugs completely segregated from other items, if so stored.

(13) The licensee holding license on Forms 9, 10, 11 and 12 shall ensure storage of expired drugs in a shelf/cupboard reserved for that purpose and labelled accordingly with red ink as "Expired Drugs" conspicuously.

(14) The registration certificate from pharmacy council of the qualified person to whom a drug sale license is issued, shall be displayed in original along with drug sale license in a conspicuous place in part of the premises at appropriate level, open and visible to the public.

(15) The licensee holding a license issued under these rules shall in no case store, sell or exhibit for sale any item, including but not limited to tobacco products, which are injurious to health.".

9. In rule 20, in sub-rule (2), for the words "sixty days", the words "thirty days" shall be substituted.

10. In Schedule A, for the existing Form 8, the following shall be substituted, namely:

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FORM NO. 8 (A)
(See rule 14 (1))

Application for the license to sell, store and exhibit for sale drugs by way of pharmacy.

1. I/We_____ of M/S _____hereby apply for **License for Pharmacy;**

2. The sale of drugs shall be under the personal supervision of; (name, registration No, NIC No & address with qualification).

   1. _____

   _____

   2. _____

   _____

3. I/We am/are submitting herewith the following documents;

   (A) testimonials of the person (s), registered under section 24(1)(a) of the Pharmacy Act 1967, who has agreed to personally supervise the sale of drugs for license in Form 12 (Pharmacy), and the proprietor (s),-

      (i) three attested copies of registration certificate issued by a pharmacy council;

      (ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs;

      (iii) in case the applicant is a company, all relevant documents pertaining to its registration;

      (iv) affidavit of the person who shall supervise the sale of drugs and the proprietor, duly verified, to the effect that they:

         (a) shall comply with the provisions of the Drugs Act, 1976 and rules framed thereunder;

         (b) have not been convicted of any offence from any Court of law;

         (c) shall inform the Licensing Authority for any change in supervisory staff etc;

         (d) are not working in any government / semi government / autonomous/private organization;

         (e) shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force; and

         (f) No drug sale license in his favour has been issued in anywhere in Pakistan which is valid till date.

   (B) plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of go-down (if any); and

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(C) treasury receipt/challan No & dated ------- amounting to Rs.------- in the specified Head of Account.

Name, address and Permanent Home Address of the person (s) who shall personally supervise the sale of drugs.

Dated:_____ Signature:----------

Name, address and Permanent Home Address of the proprietor (s)

Dated:_____ Signature:----------

FORM NO. 8 (B)
{See rule 14 (1)}

Application for the license to sell, store, exhibit for sale drugs excluding the drugs specified in Schedule "G" by way of Medical Store

1. I/We_____ of M/S_____ hereby apply for License of Medical Store;

2. The sale of drugs shall be under the personal supervision of; (Name, registration No, NIC No & address with qualification).

   1. _____

   _____

   2. _____

   _____

3. I/We am/are submitting herewith the following documents;

   (A) testimonials of the person (s), registered under section 24(1)(a) or (b) of the Pharmacy Act 1967, who shall supervise the sale of drugs for license in Form 9 (medical store) and the proprietor (s); and Testimonials of the person (s), registered under section 24(1) of the Pharmacy Act, 1967, who shall personally supervise the sale of drugs for license in Form 9 (medical store) and the proprietor (s).

   (i) three attested copies of registration certificate issued by a pharmacy council;

   (ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs;

   (iii) in case the applicant is a company, all relevant documents pertaining to its registration;

   (iv) affidavit of the person who shall supervise the sale of drugs and the proprietor, duly verified, to the effect that they:

   (a) shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

   (b) have not been convicted of any offence from any Court of law;

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(c) shall inform the Licensing Authority for any change in supervisory staff etc;

(d) are not working in any government / semi government / autonomous organization;

(e) shall not sell/stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force; and

(g) no drug sale license in his favor has been issued anywhere in Pakistan which is valid till date.

(B) plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of go-down (if any); and

(C) treasury receipt/challan No & dated ------- amounting to Rs.-------in the specified Head of Account.

(i) Name, address and Permanent Home Address of the person (s) who shall personally supervise the sale of drugs; and

Dated:_____ Signature:----------

Name, address and Permanent Home Address of the proprietor (s).

Dated:_____ Signature:----------

FORM NO. 8(C)
{See rule 14 (1)}

Application for the license to sell, store and exhibit for sale drugs by way of wholesale/distribution.

1. I/We_____ of M/S _____hereby apply for License of wholesale/Distribution;

2. The sale of drugs shall be under the personal supervision of; (name, registration No, NIC No & address with qualification).

1. _____

_____

2. _____

_____

3. I/We am/are submitting herewith the following documents;

(A) testimonials of the person (s), registered under section 24(1)(a) of the Pharmacy Act 1967, who has agreed to personally supervise the sale of drugs for license in Form 10 and the proprietor (s);

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(i) three attested copies of registration certificate issued by a pharmacy council;

(ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs;

(iii) In case the applicant is a company, all relevant documents pertaining to its registration; and

(iv) affidavit of the person who shall supervise the sale of drugs and the proprietor, duly verified, to the effect that they,-

(a) shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

(b) have not been convicted of any offence from any Court of law;

(c) shall inform the Licensing Authority for any change in supervisory staff etc;

(d) are not working in any government/semi government/ autonomous organization;

(e) shall not sell/stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force; and

(f) no drug sale license in his favor has been issued in anywhere in Pakistan which is valid till date.

(B) plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of go-down (if any) and also provide authority letter of the manufacturer(s);

(C) authority letter of the manufacturer(s); and

(D) treasury receipt/challan No & dated ------- amounting to Rs.-------in the specified Head of Account.

Name, address and Permanent Home Address of the person (s) who shall personally supervise the sale of drugs.

Dated:_____ Signature:----------

Name, address and Permanent Home Address of the proprietor (s).

Dated:_____ Signature:----------

FORM NO. 8(D)
{See rule 14 (1)}
Application for the license to sell, store, exhibit for sale drugs specified in Schedule "B"

1. I/We _____ of M/S _____hereby apply for License to sell, store or exhibit for sale drugs specified in Schedule B;

2. The sale of drugs shall be under the personal supervision of; (Name, registration No, NIC No & address with qualification).

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1. _____

_____

2. _____

_____

3. I/We am/are submitting herewith the following documents;

(A) testimonials of the person (s), registered under section 24(1)(a) or (b) of the Pharmacy Act 1967, who shall supervise the sale of drugs for license in Form 11 and the proprietor (s); and Testimonials of the person (s), registered under section 24(1) of the Pharmacy Act, 1967, who shall personally supervise the sale of drugs for license in Form 11 and the proprietor (s);

(i) three attested copies of registration certificate issued by a pharmacy council;

(ii) four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) incharge who has agreed to personally supervise the sale of the drugs;

(iii) in case the applicant is a company, all relevant documents pertaining to its registration; and

(iv) affidavit of the person who shall supervise the sale of drugs and the proprietor, duly verified, to the effect that they,-

(a) shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

(b) have not been convicted of any offence from any Court of law;

(c) shall inform the Licensing Authority for any change in supervisory staff etc;

(d) are not working in any government / semi government / autonomous organization;

(e) shall not sell/stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force ; and

(f) no drug sale license in his favor has been issued anywhere in Pakistan which is valid till date.

(B) Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of godown (if any); and

(C) treasury receipt/challan No & dated ------- amounting to Rs.-------in the specified Head of Account.

(I) Name, address and Permanent Home Address of the person(s) who shall personally supervise the sale of drugs; and

Dated:_____ Signature:----------

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Name, address and Permanent Home Address of the proprietor (s).

Dated:_____ Signature:----------

11. For the existing Schedule C, the following shall be substituted, namely:

SCHEDULE 'C'
[See Rule 11]

1.	Short conclusion/judgment (without experimentation)		Rs.50
2.	Preliminary examination of character e.g. color taste smell form solubility, miscibility, etc.		115
3.	Clarity of solution,		
	(1)	Physical Examination	70
	(2)	Chemical Examination	115
4.	Completeness of solution		150
5.	Identity test, chemical		
	(A) (a)	Inorganic substance	120
	(b)	Organic substances	125
	(B)	Unknown sample	
	(a)	Inorganic	170
	(b)	Organic	225
	(i)	Element each	150
	(i)	group each	130
6.	Leakage test Injectable		140
7.	Disintegration test, dissolution test, weight variation (uniformity of weight) uniformity of diameter, etc.		340
8.	Determination of solubility quantitatively in one solvent		260
9.	Determination of melting point		
	(a)	In-capillary	130
	(b)	In non declared substances	240
10.	Micro melting point in non-declared substance		250
11.	Crystallizing point, freezing point, setting point and solidifying point each		200
12.	Distillation range and boiling point, etc.		140
13.	Determination of water/humidity		
	(a)	In ointments.	140
	(b)	In other material	230
14.	Residue after evaporation or loss on drying Quantitatively		130
15.	Weight per ml, density, specific gravity, etc.		240
16.	Determination of viscosity		250
17.	Determination of jelly strength.		240
18.	Determination of ash, acid insoluble ash, water soluble ash sulphated ash, alcohol soluble extractive total solids, etch each.		240
19.	Readily carbonisable substances test		225

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20.	Determination of alcohol in the preparations.	160
21.	Extraction with organic solvents	290
22.	Continuous extraction of drugs	385
23.	Isolation by distillation	260
24.	Steam distillation	240
25.	Vacuum distillation	350
26.	Determination of unsaponifiabe matter free menthol, cineol, total balsamicacids, etc. Each	250
27.	Determination of Acid value, Iodine value, saponfication value Acetyl value, eaters value, etc, each	150
28.	Determination of volatile oils in drugs	170
29.	Test for the absence of	
	(a) a rachis oil in other oils	230
	(b) cotton seeds oil in other oils	230
	(c) seas am oil in other oil	230
	(d) similar other tests	230
30.	Determination of Nitrogen Kieldahi	270
31.	Determination of water Karl Fischer	285
32.	Impurity Limit test for the presence of	
	(a) ions each	250
	(b) Organic substances each	250
33.	Quantitative tests for Lead, Arsenic, Heavy metals etc.	300
34.	Determination of Foreign organic matter	250
35.	Determination of acidity or alkalinity chemical	180
36.	Determination of P.H. electrometrically.	280
37.	Test for alkalinity of glass	170
38.	Determination of	
	(a) Sulphur dioxide	160
	(b) Methoxyl	160
	(c) Absorption of carbon dioxide by soda lime	160
	(d) similar other tests	160
39.	Assay Chemical	
	(a) gravimetric each	160
	(b) Titrimetric each	260
	(c) Non aqueous titration each	260
	(d) Complexometric titration each	290
40.	Gasemetric assay	160
41.	Potentionmetric titration	150
42.	Oxygen Combustion method	150
43.	Refractomotry	230
44.	Polarimetry	140
45.	Spectrophotometery in	
	(A) Visible region	
	(a) Sample determination	360
	(b) sample Quantitative determination	390
	(c) Absorption Curves	320
	(d) Flame and atomic absorption	350
	(B) UV-Region	
	(a) Simple Determination	270
	(b) simple Quantitative determination	250
	(c) Absorption curves	240
	(C) IR-Region.	220
46.	Fluorimetry assay	390
47.	Naphelometry Assay	250
48.	Polarography every component	250

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49.	Chromatography	
	(a) paper or ion-exchange or TLC	570
	(b) Gas	460
50.	Zone Electrophoresis	270
51.	Paper Electrophoresis	310
52.	Proteolytic, amylolytic activity	270
53.	Activity of trypsin or chymotrysin	370
54.	Disinfectants/Insecticides.	
	(i) Complete chemical test	470
	(ii) Bacteriostatic / bactericidal activity	320
55.	Test for complete extraction of alkaloids	630
56.	Test for complete extraction of dextrants	440
57.	Saponification	250
58.	Surgical ligatures and sutures	
	(a) Measurement of length	130
	(b) Measurement of Diameter	130
	(c) Tensile strength	140
	(d) Softening point	130
	(e) other test	250
59.	Surgical dressing etc.	
	(a) determination of Yarn number each	220
	(b) Thread count (warp and weft) etc.	120
	(c) Elasticity	120
	(d) Wt. Per unit area	130
	(e) determination of content of wool	230
	(f) setting time	120
	(g) other chemical test each	230
	(h) Absorbency	220
	(i) Naps etc.	120
	(j) Adhesive strength of plasters	120
	(k) other tests	150
60.	Determination of starch in dressing	230
61.	Identity test in vegetable drugs	530
	(a) Pharmacopoeial each -	
	(b) Non official each -	
62.	Identity test in Pulverized drugs in mixture	550
	(a) Official drugs each -	
	(b) Non official each -	
63.	Un known vegetable drugs -	
64.	Microscopic evaluation	250
65.	Syringability test	220
66.	Air Tightness	250
67.	Microbiological tests -	
	(i) Sterility of Antibiotics, plasma and other blood preparations	770
	(ii) sterility test –	
	(iii) sterility of sutures –	
	(iv) Vaccines and Sera etc. –	
	(v) test for presence of fungi etc. –	
68.	Test for infusion bags microbiological	790
69.	Activity, potency test.	250
	(i) Antibiotics per ingredients	330
	(ii) vitamin etc.	350

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70.	Other bacteriological examination	370
71.	Toxicity/abnormal toxicity /undue, toxicity safety test	320
72.	Depressor substances test	320
73.	Presser substance test	360
74.	Biological adequacy test	400
75.	Biological assay	360
76.	Pyrogen test	360
77.	Other pharmacological test	250
78.	Clinical pharmacological trials	250

Note: 1. The exact fee by the Incharge of the Laboratory on the basis of time spent, reagents/chemicals etc used for the conduct of test and analysis

2. Fee for the other tests not given above is to be calculated by the incharge of the Laboratory.

12. For the existing Schedule F, the following shall be substituted, namely:

SCHEDULE 'F'
[See Rule 18(1) (c)]

LIST OF MINIMUM REQUIREMENTS FOR PHARMACY:

1. **Covered Area:** The covered area of the premises of a Pharmacy shall not be less than 300 square feet with minimum breadth of 12 feet in front and height of 8 feet. In case dispensing/compounding is carried out, the sign board of pharmacy shall beer an inscription "Dispensing/Compounding Facility".

2. **Premises:** The premises shall be separated from room for private use. The premises shall be built dry, well lit and ventilated and shall of sufficient dimensions to allow the goods in stock, especially drugs and poison to be kept in a clearly visible and appropriate manner. The area of the section to be used at dispensing department shall not be less than 6 sq Meters for one person working therein with additional 2 sq Meters for each additional person. The height of the premises shall at least be 2.5 sq Meters. The floor shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth durable and washable surface devoid of holes cracks. A facility shall be provided with good quality of water. The dispensing department shall be separated by a barrier to prevent the entry of public.

3. **Furniture & Apparatus:** The furniture and apparatus shall be adapted to the uses for which they are intended and correspond to the size and requirement of the establishment. The drugs and chemicals shall be kept in separate almirah/cupboard or a room appropriate to their properties and in such special containers as shall prevent any deterioration of contents or of contents of containers kept near them. Drawer glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust. Every container shall bear label of appropriate size, easily readable, with names of medicaments as given in Pharmacopoeias.

A facility shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastics etc. The containers of concentrated solutions shall bear special label or marked with the word "Poison" in red letters on a white background. A Pharmacy shall be provided with the following minimum apparatus and books necessary for masking of official preparation and prescriptions:

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4. **Extent of dispensing/compounding:** The facility shall be used only for compounding/dispensing of topical preparations including creams, ointments, lotions etc in quantities as required in the prescription issued by the registered medical practitioner.

5. **Apparatus:** Balances with dispensing sensitivity of 30 mg Balances Counter, capacity 3 kg, sensitivity 1 gm Beakers lipped, assorted sizes Bottles prescription, un graduated assorted size Choric extractors Evaporating dishes, porcelain Filter papers, Funnels, Glasses Litmus papers, blue and red Measure glasses cylindrical 10ml, 25ml, 100ml and 500ml Mortar and pestle glass Ointment slab, porcelain, Ointment pot with bakelite or suitable cap. Pipettes graduated, 2ml, 5ml and 10 ml Ring stand (retort) iron, complete with rings Rubber stamps and pad, scissors, spatula Spirit lamp or gas burner Glass stirring rods, Thermometers, 0 to 200C Tripot stand, Watch glasses, Water bath Water distillation still in case eye drops are prepared Weight metric, 1mg to 100mg Wire gauze, Pill finisher, Boxwood Pills Machine, Pill box and suppository mould.

6. **Books:** The United State Pharmacopoeia or British Pharmacopoeia (Current Edition) National Formulary of Pakistan (Current Edition) The Drugs Act, 1976 and rules framed there under The Pharmacy Act, 1967 The Dangerous Drug Act and CNS Act, 1997 Any other relevant book.

7. **General Provisions:** Dispensing/compounding of drugs shall be conducted *under the continuous personal supervision* of a qualified person referred to in rule 19 whose name shall be displayed conspicuously in the premises and his registration certificate issued by the pharmacy council shall be displayed in the premises. The qualified person shall always put on clean white overalls. The premises and the fittings of the facility shall be properly kept and maintained and everything must be in good order and clean. All records and register shall be maintained in accordance with the laws in force. Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person. Drugs when supplied shall have labels conforming to the provisions of laws in force.

Note: The above requirements are subject to modification on the directions of the Licensing Authority, if the Authority is of the opinion that having regards to the nature of drugs dispensed, compounded or prepared by the licensee it is necessary to relax the above requirements in the circumstances of a particular case.

13. After Schedule F, the following new Schedules shall be added, namely:

Schedule G
[See rule 19(1)(d)]

Drugs Not To Be Sold/Stored By Licensee In Form No. 9;

1. Antileprosy

i. Rifampicin Injection ii. Dapsone iii. Clofamazine
iv. Ethionamide v. Prothionemide

2. Immunological products, Vaccines, Sera / Anti Sera

i.. Anthrax Vaccine Ix Rubella Vaccine
ii. BCG Vaccine X Pneumococcal vaccine
iii Botulisms Antitoxin Xi Poliomyelitis Vaccine

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iv. Cholera Vaccine xii Smallpox Vaccine
v. Diphtheria Vaccine xiii Typhoid Vaccine
vi. Influenza Vaccine xiv Immunoglobulins
vii. Measles Vaccine xv Rabies Vaccine
viii. MMR Vaccine xvi Homophiles Influenza Type B Vaccine

3. **Products Related with Malignant Diseases and Immunosupression**

i. Folinic Acid ii. Doxorubicin HCl iii. Mercaptopurine iv. Thioguanine v. Vincristine vi. Cisplastin vii. Busulphan viii. Carmustine ix. Lomustine x. Cyclophosphamide xi. Melphalan xii. Fluorouracil xiii. Mitozantrone xiv. Methotrexate xv. Vinblastine xv. Carboplatin xvii. Bleoimycin xviii. Dactinomycin xix. Chlorambucil xx. Dacarbazine xxi. Amasascrine xxii. Azathioprine xxiii. Cyclosporin etc

4. **Drugs of Anesthesia and Inhalation Anesthetics**

i. Propofol
ii. Enfluran
iii. Isofluran
iv. Halothane
v. Bupivacain
vi. Thiopentone
vii. Benzodiazepine
viii. Mitazolam
Ix. Naloxone HCl
xv. Vancuronium
xi. Pancuronium
xii. Tubocuraine
xiii. Suxamethonium
xiv. Neostigmine

5. **Antibiotics**

i. Spectinomycin ii. Vancomycin iii. Teicoplanon iv. Colistin v. Sodium Fusidate vi. Imipenem

6. **Inotropics**

i. Primacor ii. Milrinone iii. Enoximone

7. **Injection Prostaglandins**

i. Dinoprostone ii. Carboprost iii. Gemeprost

8. **Alpha Blocker**

i. Prazosin HCl ii. Indoramine iii. Daxazosing iv. Alfuzosin

9. **Biotechnological Products**

i. Interferon ii. Erythropoetin

10. **Narcotics, Psychotropic / Tri Cyclic Anti Depressant**

i. Morphine
ii. Buprenorphine
iii. Nalbuphine
iv. Fantanil
v. Pethidine
vi. Lorazepam
vii. Temazepam
viii. Oxazepam
xviii. Chlorpromazine
xix. Meprobamate
xx. Chlordiazepoxide
xxi. Alprozolam
xxii. Clonazepam
xxiii. Flurazepam
xxiv. Loprazolam
xxv. Dothiepin

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ix. Amoxapine
x. Iprine Dole Codeine
xi. Pentazocine
xii. Phenelzine
xiii. Lithium
xiv. Dextropropoxyphene
xv. Clomipramine
xvi. Mianserin
xvii. Maprotiline
xxvi. Doxepin
xxvii. Nortriptyline
xxviii. Trimipramine
xxix. Tranycypromine
xxx. Flupenthixol
xxxi Tryptophan
xxxii. Imipramine
xxxiii. Amipriptyline etc

11. **Antiviral**

i. Acyclovir
ii. Amantadine HCl
iii. Famciclovir
iv. Inosine Pranolsex
v. Zidovudine
vi. Ganciclovir
vii. Idoxuridine
viii. Ribavirin
ix. Vidarabin
x. Trifluridine
xi. Methisozone etc

12. **Thrombolytic Enzymes**

i. Alteplase ii. Anislreplase iii. Streptokinase
iv. Urokinase

13. **Product Used In Dialysis**

i. Peritoneal Dialysis & Haemodialysis
ii. Lysine Solution (Irrigation Solution)
iii. Hyper tonic Solution Iv Isotonic Solution

14. **Creams and aerosols Steroidal Preparations**

i. Prednisolone
ii. Methylprednislone
iii. Triamcinolone
iv. Dexamethasone
v. Beclomethasone
vi. Hydrocortisone

15. **Hormones**

i. Vasopressin
ii. Finasteriode
iii. Desmopressin
iv. Stanozolol
v. Somatropin
vi. Nandrolone
vii. Testosterone
viii. Mesterolone
ix. Progesterone's

Note: The Secretary to Government of Khyber Pakhtunkhwa, Health Department may, on the recommendations of the Provincial Quality Control Board, by notification in the official gazette, declare any drug to be schedule G drug for the purposes of these rules.

Schedule H
[See Rule 18(1)(f)]

REQUIREMENT FOR THE LICENSEE IN FORM NO.10 FOR THE DISTRIBUTION/WHOLESALE OF DRUGS.

(i) The person (s) registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs;

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(ii) A sign board having minimum length 5 feet and width of 2.5 feet in black writing on a yellow colored shall be displayed on the front side;

(iii) The licensee shall maintain area sufficient for the storage of the drugs intended to be sold/distributed but shall in no case be less than 144 Sq Ft with minimum breath of 12 feet;

(iv) Steel racks/pellets shall be made available for the storage of drugs;

(v) Drugs shall be stored in a way that suitable distance shall be maintained form the walls and floor;

(vi) Air conditioner/air handling unit shall be provided for the maintaining room temperature, however, cold storage arrangements shall have to be put in place in case the licensee is dealing with drugs requiring temperature 2 to 8 C;

(vii) Accounts/admin office shall be established with computer facility for updated record of sale/purchase of pharmaceuticals.

(viii) Authority letter of the manufacturer(s) must be displayed.

(ix) For the safe delivery of drugs to the sale outlets, the delivery van must be air conditioned for preserving the properties of the content throughout the period during which it remained in possession of the supplier.

(x) The premises should be located in commercial area/building at preferably be at ground floor.

(xi) The sale/supply should be according to the Rules/Act and notifications issued from time to time.

(xii) For drugs requiring special storage condition, proper storage must be ensured.

(xiii) This license and registration certificate (from pharmacy council) of the person(s), personally supervising the sale of drugs shall be displayed in a prominent place in part of the premises at appropriate level, open and visible to the public.

(xiv) The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules framed there under for the time being in force.

(xv) The licensee shall report forthwith to the Licensing Authority and Drug Inspector, in case of any change in person (s) incharge, personally supervising the sale of drugs.

(xvi) No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it remained in possession of the licensee.

(xvii) The supply of a drug shall be recorded suitably and the records, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale;

(xviii) The licensee shall ensure that warranty in the prescribed form is issued to the purchaser for every batch of drug in compliance with the provisions of the section 23(1)(i) of the Drug Act, 1976.

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(xix) The licensee shall ensure that warranty in the prescribed form is obtained from the manufacturer or importer for every batch of drug so procured in compliance with the provisions of the section 23(1)(i) of the Drug Act, 1976.

SECRETARY TO
GOVT. OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

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